

REMARKS

Reconsideration and continuing examination of the above-identified application is respectfully requested in view of the amendments above and the discussion that follows.

Claims 1-20, 22-26, 28 and 32-44 were cancelled. Claims 45-49 have been added as discussed below. Claims 21, 27 and 29-31 and 27 have been amended pursuant to the Examiner's helpful suggestion. Claims 21, 27, 29-31 and 45-49 are in the case and are before the Examiner.

The Examiner is thanked for the courtesies extended to counsel during the telephone interview of 13 December 2005. Her comments regarding divisional applications dealing with claims directed to nucleic acids are being heeded with new filings coming shortly.

I. The Amendments

Claim 21 has been amended to clarify that a claimed polypeptide is recombinantly expressed in a host cell and to limit the claimed sequences to those of KLH1. Specific support for the claim language can be found at least on pages 11, 13 and 17 as well as in the originally filed Abstract. Specific support for the added subparagraph reciting sequence homology can be found at least at pages 14 and 15 of the specification. The amendments to the first words of claims 27 and 29-31 are designed to bring the claims into closer concert with the US form of claiming.

New claims 45-49 are similar to claims 38-42 of the co-assigned companion application Serial No. 10/049,988 that relates to KLH2. These claims are supported at least by the

disclosures of pages 17-19 and claims 34-39 of the present application.

It is thus seen that no new matter has been added.

## II. The Action

### A. Rejection Under 35 USC §112, First Paragraph

The claims were rejected as allegedly failing the "description requirement" of Section 112, first paragraph. The central issue of the rejection dealt with "fragments" of the recited polypeptides, and it is believed that that basis for rejection is now moot in view of the present amendments.

### B. Rejection Under 35 USC §102

The claims were rejected under 35 USC §102 as allegedly anticipated by the teachings of Harris et al. (hereinafter Harris) who taught the isolation of full length KLH1 and KLH2 from *M. crenulata*. This basis for rejection cannot be agreed with and is respectfully traversed. The previous rejection based on the disclosures of Söhnngen et al. has been withdrawn because it was noted the teaching disclosed incomplete recovery of the entire domain. The discussion that follows is relevant to both teachings from an anticipation or obviousness point of view.

The Examiner's attention is invited to the enclosed Declaration of Jurgen Markl, one of the named inventors. The inventor notes that no one has yet cloned any protein in cells of *M. crenulata*, that the pattern of glycosylation in KLH1 and KLH2 is unique and unusual. Papers published in refereed journals are enclosed with that Declaration that support his statements. See, for example, the Abstract of Kurokawa et al.,

which includes Dr. Markl as a co-author, that ends with the statement:

"[h]ence, our studies demonstrate that this marine mollusk glycoprotein is characterized by a unique oligosaccharide pattern comprising, in part, novel structural elements."

Dr Markl concludes in his Declaration that because there has been no known expression of any protein in cells of *Megathura crenulata* and because of the unique and unusual character of the glycosylation pattern of native KLH1 and KLH2 produced by *Megathura crenulata*, a presently claimed polypeptide cannot be the same as that obtained from *Megathura crenulata* and must therefore be novel over the art of record. Put differently, because no one knows how to express a protein in *Megathura crenulata* cells, those cells cannot be a "suitable host cell" as required by the claim. Still further, because the glycosylation pattern is unusual and unique, it will not be reproduced in any other known host cell. Again, therefore, the claimed subject matter is novel.

This basis for rejection should therefore be withdrawn.

### III. Summary

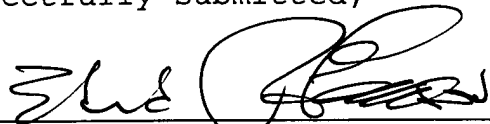
Claims 1-20, 22-26, 28 and 32-44 were cancelled. Claims 45-49 have been added. Claims 21, 27 and 29-31 and 27 have been amended pursuant to the Examiner's helpful suggestion. Each basis for rejection or objection has been dealt with and overcome or otherwise made moot.

It is believed that this application is in condition for allowance of all of the pending claims. An early notice to that effect is earnestly solicited.

No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,


By   
Edward P. Gamson, Reg. No. 29,381

WELSH & KATZ, LTD.  
120 South Riverside Plaza, 22nd Floor  
Chicago, Illinois 60606  
Phone (312) 655-1500  
Fax No. (312) 655-1501

Enclosure  
Declaration and art  
Form 1449

CERTIFICATE OF MAILING

I hereby certify that this Reply and Amendment, along with a Declaration by and inventor and art are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on March 28, 2006.

By   
Edward P. Gamson